

DEC 30 2004

**510(K) SUMMARY**

**Manufacturer:** Barco NV Barcovieu  
Theodoor Sevenslaan 106  
8500 Kortrijk  
Belgium

**Submitted By:** Ferguson Medical  
Consultant to Barco NV

**Contact Information:** Phone: +32(0) 56 23 32 11  
FAX: +32(0) 56 23 3 74

**Classification Name:** System, image processing

**Common/Usual Name:** Image display system, medical image  
workstation, image monitor/display, and others

**Proprietary Name:** Coronis 5MP Medical Flat Panel Display System

**Classification Number:** 21 CFR 892.2050/Procode 90LLZ

**Substantial Equivalence:** Coronis 5MP Medical Flat Panel Display System  
(K013922), Dome CX Digital Flat Panel Display  
System, Model C5i (K040443) and others

**Device Description:** The Coronis 5MP device is a digital image  
display system

**Intended Use:** The Coronis 5MP Medical Flat Panel Display  
System is intended to be used in displaying  
and viewing digital images, including digital  
mammography, for review by trained medical  
practitioners.

**Technological Characteristics:** The Coronis 5MP device consists of  
components to provide high resolution  
visualization of digital images.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 30 2004

Barco NV Barcoviev  
c/o Mr. Frank Ferguson  
Ferguson Medical  
12200 Academy Road NE #931  
ALBUQUERQUE NM 87111

K042221  
Device Name: Coronis 5MP Medical Flat  
Panel Display System  
Regulation Number: 21 CFR 892.2050  
Regulatory Class: Class II  
Product Code: LLZ  
Dated: December 14, 2004  
Received: December 16, 2004

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

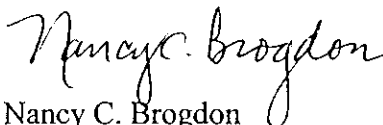
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): K042221

Device Name: Coronis 5MP Medical Flat Panel Display System


Indications For Use:

The Coronis 5MP Medical Flat Panel Display System is intended to be used as a tool in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of Reproductive, Abdominal,**  
**and Radiological Devices**  
510(k) Number K042221

Prescription Use XX  
(Per 21 CFR 801.109)

OR

Over-The- Counter Use \_\_\_\_\_